Clinical Trials Sponsorship by Academic and Research Institutes: Challenges and Opportunities

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SPONSOR

The person/Organisation/Institution who takes on ultimate responsibility for the initiation, management, financing [or arranging the financing] of a clinical trial (ICH GCP).

AND

Responsibility to support the independent researcher to achieve rigorous research to international standards
Challenges in North-South collaborative research: Regulatory Oversight

- Multiple/Absent regulatory/ethics procedures
  - Large admin load/cost
  - Time reqd frequently underestimated

- Varying levels of regulatory “stringency” (WHO 2010) → risk of reduced protection

- Variable approval times for EC on average 5 mtnths and 8-18mnths for National Authority approval (Geldenhuys et al., 2013)
Regulatory Oversight

- Level of risk not accommodated
- Focus often rest on procedural requirements and runs the risk of missing potential ethical issues.
Challenges: GCP/GCLP

Burden of Duty

• GCP (WHO 1995, ICH 1996) and GCLP (WHO 2009) achieved with multiple highly skilled team members – stringent

• Variable level of awareness and financial/human resources to raise standards
  – Reality is small teams with extended roles.
  – Often limited, ad hoc training

• Site resources - often minimal equipment and unfunded core staff in trial units.
Challenges: GCP/GCLP

- Data Management
  - limited GCP compliant open access systems
  - unstable internet connections
  - limited trained staff necessary to develop/validate databases, and to check systems (data review)
  - One size won't fit all but a database of proven systems might harmonise practice better.
Challenges: Monitoring

• Extremely useful for early detection of training and resource needs:

BUT

• External monitoring is costly

• Extent of monitoring input required often lacks:
  – Contextual considerations
  – Risk evaluation

Commonly underfunded
Challenges: Clinical Trial Insurance

Insurance Cover

• Professional Indemnity (Registered Professional Cover) - Clinical negligence

What level of cover is there?

• No-fault Indemnity (Trial Related)
  – Sponsor provided – varies and relevance to international sites/participants often unknown
  – Shortage of companies
  – Lack of agreed models/good practices
  – Agreeing exclusions/excess payable
Summary

• Non-commercial sponsors deal with the challenges of academic research, plus additional context-related challenges

• Limited sponsor infrastructure often means either expensive outsourcing or gaps in the quality system

• Need for adapted approaches/tools for ensuring full protection of subjects/populations and compliance with research standards
Opportunity 1: Translating capacity development programme into practice

• Define need in EDCTP funded teams in Africa

• Sustainability
  – Retention of skilled staff
  – Career progression
  – Performance enhancement

• Establish a South-South exchange programme.
Opportunity 2: Develop a database of Clinical Trial Insurance

- Adequate and fair compensation to trial participants in case of harm (Helsinki, 2013)
- Scope current contracts and companies providing indemnity
- Define key differences
- Identify potential risks
- Develop a model template for guidance with EDCTP appointed specialist
Opportunity 3: Define and agree internal and reciprocal monitoring systems

- Scope current systems/SOPs utilised by sponsors
- Draw up and agree guidelines for internal monitoring
- Draw up and agree guidelines for reciprocal monitoring between studies/sponsors
- Establish a training programme and training team
Opportunity 4: To share information on data management tools

• Scope current systems

• Identify good practices for different study designs

• Promote the exchange of information regarding off-line open access database systems
Opportunity 5: Donor - Sponsor relationship

• Helsinki (2013)
  – Access to intervention shown to be effective after the trial.

• Fill gaps in support from other granting bodies eg. staff salaries

• Establish sponsors in the South:
  – What are the core set of resources needed to assume the role?
  – Awareness raising and training
Running trials in resource poor settings is getting more complicated.

Non-commercial Sponsors should take every opportunity to work with EDCTP partners to continue to enable patient- and community-centered quality research of relevance in Africa.
THANK YOU